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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,830	10/01/2001	Akira Miyake	Q66067	3999

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SUGHRUE, MIOIN, ZINN,
MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, N.W.
Washington, DC 20037-3213

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,830

Applicant(s)

MIYAKE ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 16-19 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 15 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 10,15 and 20, drawn to a method of screening for compounds and peptides capable of modifying the activity of a potassium channel protein in Paper No. 6 (4/16/03) is acknowledged. Claims 11-14, 16-19 and 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6 (4/16/03). In addition, Applicant elects the polynucleotide comprising the 6th to 3257th nucleotides of the polynucleotide set forth in SEQ ID NO: 1 for further examination.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Priority

3. Applicant is required to update the allowed patent information.

Drawings

4. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10,15 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 10,15 and 20 are rejected as vague and indefinite for reciting the term "index of modification" because the term "index of modification" is not defined in the specification. It is further unclear how an index of modification of a potassium channel protein may be affected in response to a physiological characteristic of the potassium channel.

5b. Claims 10, 15 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The instant claims are directed to screening for compounds and peptides capable of modifying the activity of a potassium channel. However, there is no correlation between the modification and measuring the index. It is also unclear what index is measured and how it is measured? In addition, it is unclear what is the base level of activity.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6a. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses the nucleotide encoding the potassium channel polypeptide (SEQ ID NO: 1 or 5 or degenerate with respect to the isolated polynucleotide molecule encoding potassium channel polypeptide). This meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the specification does not disclose all the polynucleotide sequences that hybridize to SEQ ID NO: 1. The specification does not define what is meant by the generic term "potassium channel protein" and discloses potassium channel polypeptides encoded by SEQ ID Nos: 1 or 5 or degenerate variants only. There is no description of what physiological characteristics makes a potassium channel polypeptide a potassium channel, any potassium channel from other species, or anything else that would be considered a "potassium channel". The claims as written, therefore, encompass nucleotide sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph. The specification does not provide written to support the genus encompassed by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the nucleotide encoding the potassium channel polypeptide (SEQ ID NO: 1 or 5 or degenerate with respect to the isolated polynucleotide molecule

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encoding potassium channel polypeptide), the skilled artisan cannot envision all the detailed chemical structure of the claimed nucleotide sequences, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only the nucleotide encoding the potassium channel polypeptide (SEQ ID NO: 1 or 5 or degenerate with respect to the isolated polynucleotide molecule encoding potassium channel polypeptide), but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed is not representative of the genus because the genus is unclear and potentially highly variant. As a result, it does not appear that the inventors were in possession of the scope of nucleotide sequences set forth in claim 10.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

6b. Claims 10, 15 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for measuring channel activity of potassium

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channel does not reasonably provide enablement for modifying the activity of a potassium channel protein in response to a physiological characteristic of the potassium channel protein. In addition, the specification while being enabling for nucleotide encoding the potassium channel polypeptide (SEQ ID NO: 1 or 5 or degenerate with respect to the isolated polynucleotide molecule encoding potassium channel polypeptide) does not provide enablement for all potassium channel molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification as filed is insufficient to enable one skilled in the art to practice the claimed invention without an undue amount of experimentation. The measuring of channel activity does not reasonably provide enablement for the scope of modifying the

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activity of a potassium channel protein in response to a physiological characteristic of the potassium channel protein and thus measuring the index. Applicants have demonstrated the channel activity (Example 5 and 6, pages 39-41). However, it is unclear how and what other biological activity of the potassium channel protein maybe modified in order to screen for compounds capable of such modification. In addition, there is no guidance provided for the mechanism for modifying the activity of the channel protein either. While mechanism is not required, it can allow extrapolation of enablement to non-exemplified embodiments. Since applicant has not provided any working examples to indicate modifying the activity of a potassium channel protein in response to a physiological characteristic of the potassium channel protein either *in vitro* or *in vivo*, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

Given the breadth of claims 10, 15 and 20 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for modifying the activity of a potassium channel protein in response to a physiological characteristic of the potassium channel protein.

7. The art made of record and not relied upon is considered pertinent to applicant's disclosure. Akira et al. (U.S. Patent No. 6,236, 168) teaches a brain specific potassium channel protein. The instant application is a continuation of the allowed pattern.

8. No Claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
June 17, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600